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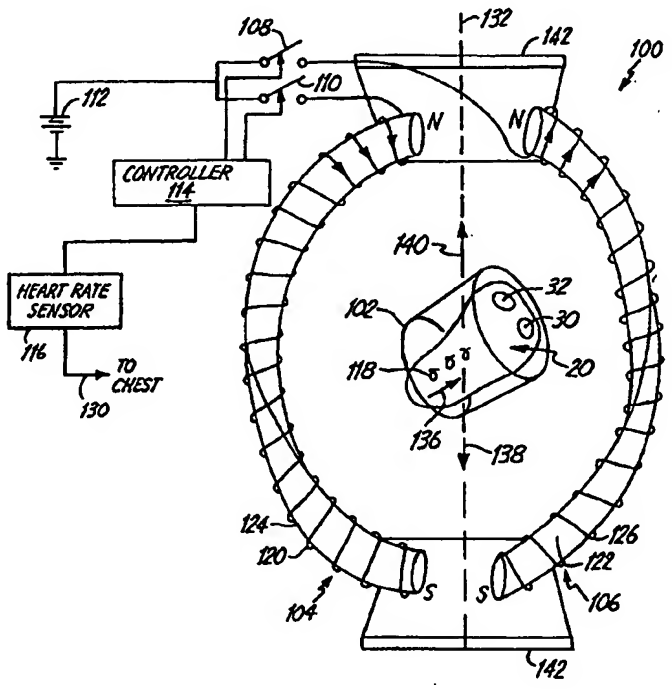
(54) Title: CARDIAC ASSIST DEVICE USING FLUID

(57) Abstract

A cardiac assist device and method of use for assisting the function of a heart (20). The assist device includes a compressor (102) positioned against the epicardial wall of the heart (20) and a field generator (104, 106) for driving a fluid coupled to the compressor to exert pressure on the heart (20). The field generator (104, 106) may be a magnetic field generator and the fluid coupled to the compressor (102) may be a ferrofluid. The compressor (102) may include two containment regions (146, 148) containing ferrofluid on opposite sides of the heart (20), and a pair of compression portions (150, 152) coupled to the containment regions (146, 148). The filled generator may be electromagnetic which includes two electromagnets (104, 106) having corresponding core portions and corresponding coils. The electromagnets (104, 106) may be disposed with their north and south poles in alignment and separated by a gap to allow relative movement. The electromagnets (104, 106) may be external or internal to the body.



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CARDIAC ASSIST DEVICE USING FLUID

BACKGROUND OF THE INVENTION

The present invention deals with a ventricular assist device. More particularly, the present invention deals with cardiomyoplasty using a ferro fluid or other similar fluid.

A number of different types of coronary disease can require ventricular assist. Present ventricular assist devices (VADs) employ mechanical pumps to circulate blood through the vasculature. These pumps are typically plumbed between the apex of the left ventricle and the aortic arch (for LVADs), and provide mechanical assistance to a weak heart. These devices must be compatible with the blood, and inhibit thrombus formation, due to the intimate contact between the pump components and the blood.

Cardiomyoplasty is a form of ventricular assist which includes squeezing the heart from the epicardial surface to assist the ejection of blood from the ventricles during systole. This form of ventricular assist does not require contact with blood or surgical entry into the cardiovascular system. It has been expressed in several embodiments over the years. The first involves an approach which is drastically different from the mechanical pump approach discussed above. The approach uses a muscle in the patient's back. The muscle is detached and wrapped around the epicardium of the heart. The muscle is then trained to contract in synchrony with the ECG pulse, or other pulse (which may be generated by a pacemaker). Since the back muscle does not contact blood, many of the issues faced by conventional LVADs are avoided. However, this approach also suffers from disadvantages, because operation of the muscle tissues is poorly understood and largely uncontrolled.

A number of other methods are also taught by prior references. Some such references disclose balloons or bellows which squeeze on the exterior surface of the heart in synchrony with the ECG signal. U.S. patent number 3,455,298 to Anstadt discloses an air pressure source which is used to inflate a balloon about a portion of the external surface of the heart, in order to provide a squeezing pressure on the heart.

Other references disclose similar items which are inflated using fluid inflation devices. Still other references disclose mechanical means which apply pressure radially inwardly on the epicardial surface of the heart. For instance, U.S. patent number 4,621,617 to Sharma discloses an electromechanical mechanism for applying external pressure to the heart.

The air and fluid inflation devices exhibit certain advantages in that they use conformable fluids to provide an atraumatic squeezing force on the surface of the heart, as opposed to mechanical and electromechanical devices which use rigid surfaces, which contact the heart, in order to exert the squeezing force. However, one disadvantage of the fluid devices is the need for a pump which delivers fluid from a reservoir. The pump and the associated electronics is generally bulky, and can be too large and cumbersome to be implanted within the patient. Thus, such devices often require the patient to remain in bed while the device is in use.

Further, while the human muscle wrap approach does address some of these problems, it requires radical surgery plus the training of the muscle, which may not always be accomplished successfully.

SUMMARY OF THE INVENTION

The present invention is directed to a cardiac assist device for assisting the function of a heart. The assist device includes a compressor positioned against the epicardial wall of the heart and a field generator for driving a fluid coupled to the compressor to exert pressure on the heart. The pressure exerted against the heart improves heart function.

The field generator may be a magnetic field generator and the fluid coupled to the compressor may be a ferrofluid. The magnetic field generator may include an electromagnet having a core and an energizeable coil disposed thereabout. The ferrofluid may be disposed proximate a gap in the electromagnet such that the compressor exerts a force against the heart wall by generation of a magnetic field in the gap.

The compressor may include two containment regions containing ferrofluid on opposite sides of the heart, and a pair of compression portions coupled to the containment regions. The electromagnet may include two electromagnets having corresponding core portions and corresponding coils. The electromagnets may be disposed with their north and south poles in alignment and separated by a gap to allow relative movement. The electromagnets may be external or internal to the body.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a partial sectional view of a human heart and its associated proximate vascular system.

FIG. 2 is a diagrammatic illustration, in partial schematic form, of an assist device in accordance with one aspect of the present invention.

FIG. 3 is a top view of the device shown in FIG. 2.

FIGS. 4A-4C illustrate an assist device in accordance with another aspect of the present invention.

FIGS. 5A-5C illustrate an assist device in accordance with another aspect of the present invention.

FIGS. 6A-6C illustrate an assist device in accordance with another aspect of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a partially sectioned view of a human heart 20, and its associated vasculature. The heart 20 is subdivided by muscular septum 22 into two lateral halves, which are named respectively right 23 and left 24. A transverse constriction subdivides each half of the heart into two cavities, or chambers. The upper chambers consist of the left and right atria 26, 28 which collect blood. The lower chambers consist of the left and right ventricles 30, 32 which pump blood. The arrows 34 indicate the direction of blood flow through the heart. The chambers are defined by the epicardial wall of the heart.

The right atrium 28 communicates with the right ventricle 32 by the tricuspid valve 36. The left atrium 26 communicates with the left ventricle 30 by the mitral valve 38. The right ventricle 32 empties into the pulmonary artery 40 by way of the pulmonary valve 42. The left ventricle 30 empties into the aorta 44 by way of the aortic valve 46.

The circulation of the heart 20 consists of two components. First is the functional circulation of the heart 20, i.e., the blood flow through the heart 20 from which blood is pumped to the lungs and the body in general. Second is the coronary circulation, i.e., the blood supply to the structures and muscles of the heart 20 itself.

The functional circulation of the heart 20 pumps blood to the body in general, i.e., the systematic circulation, and to the lungs for oxygenation, i.e., the pulmonic and pulmonary circulation. The left side of the heart 24 supplies the systemic circulation. The right side 23 of the heart supplies the lungs with blood for oxygenation. Deoxygenated blood from the systematic circulation is returned to the heart 20 and is supplied to the right atrium 28 by the superior and inferior venae cavae 48, 50. The heart 20 pumps the deoxygenated blood into the lungs for oxygenation by way of the main pulmonary artery 40. The main pulmonary artery 40 separates into the right and left pulmonary arteries, 52, 54 which circulate to the right and left lungs, respectively. Oxygenated blood returns to the heart 20 at the left atrium 26 via four pulmonary veins 56 (of which two are shown). The blood then flows to the left ventricle 30 where it is pumped into the aorta 44, which supplies the body with oxygenated blood.

The functional circulation, however, does not supply blood to the heart muscle or structures. Therefore, functional circulation does not supply oxygen or nutrients to the heart 20 itself. The actual blood supply to the heart structure, i.e., the oxygen and nutrient supply, is provided by the coronary circulation of the heart, consisting of coronary arteries, indicated generally at 58, and cardiac veins. Coronary artery 58 resides closely proximate the endocardial wall of heart 24. The coronary artery 58 includes a proximal arterial bed 76 and a distal arterial bed 78 downstream from the proximal bed 76.

In order to assist the heart, the present invention provides a fluid either partially surrounding the heart, or completely surrounding the heart, wherein

the fluid can be influenced by electric or magnetic fields. The fluid is located closely proximate the epicardial surface of the heart and is influenced by the application of an electric or magnetic field in order to assist the heart.

FIG. 2 is a diagram, in partial schematic form, illustrating cardiomyoplasty system 100 which is used, in accordance with one aspect of the present invention, in order to assist the heart 20. In system 100, heart 20 is illustrated surrounded by a bag 102 which is substantially, or partially, filled with a ferrofluid (shown in FIG. 3). System 100 also includes electromagnet sections 104 and 106 which are coupled, through switches 108 and 110, to a power supply 112. Switches 108 and 110 are controlled by controller 114 which, in one preferred embodiment, receives an ECG input signal from heart rate sensor 116.

In one preferred embodiment, bag 102 is formed of a non-compliant balloon material which is preferably attached to portions of the heart by sutures, indicated generally at 118. Bag 102 is filled with a ferrofluid which, in one preferred embodiment, is paramagnetic in that it becomes magnetic in the presence of an applied magnetic field. Such fluids are commercially available from Ferrofluidics Corporation, 40 Simon Street, Nashua, New Hampshire 03061, and Lord Corporation, 405 Gregson Drive, Cary, North Carolina 27511. The fluid is preferably biocompatible and includes suspensions of small, ferromagnetic particles. In zero applied field, the fluid is non-magnetic. However, the fluid becomes magnetized when an external magnetic field is applied. The maximum magnetization which can occur in the fluid is referred to as the saturation induction, and is typically achieved in applied fields of about 1000

Oersteds, and has typical values of about 1000 Gauss. Applied fields in this range, and higher, can be achieved with electromagnets using conventional core materials and fairly modest electrical power.

The ferrofluids surrounding the heart are energized by magnetic fields which can originate from electric currents or permanent magnets situated either within or outside the body. For example, the magnetic fields in FIG. 2 are generated by electromagnets 104 and 106 located outside the body. Electromagnets 104 and 106 each include a coil 120 and 122, respectively which is formed, illustratively, of insulated copper wire. Coils 120 and 122 are wound around thin sheets of magnetic material 124 and 126, respectively. The material 124 and 126, in one preferred embodiment, is commercially available under the commercial designation Hiperco, from Carpenter Metals, of Reading, Pennsylvania. In the embodiment illustrated in FIG. 2, electromagnets 104 and 106 are generally semi-circular in shape, and are each configured as half torroids set up in a repulsion configuration.

Coils 120 and 122 are coupled to power supply 112 (which in one preferred embodiment is a battery) through switches 108 and 110, which are controlled by controller 114. A bipolar ECG lead 130 is attached at a point on the patient's chest and provides a signal to heart rate sensor 116 which, in turn, provides a signal to controller 114 indicative of the activity of heart 20. Controller 114 controls switches 108 and 110 to selectively energize coils 120 and 122 during systole.

When current is passed through coils 120 and 122, in the direction indicated, a magnetic field is directed through the chest of the patient from the north poles (indicated by the letter N in FIG. 2) to the south